#14
Rec'd 3/14/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Ashkenazi et al.
App. No.	:	09/902,759
Filed	:	July 10, 2001
For	:	SECRETED AND TRANSMEMBRANE POLYPEPTIDES AND NUCLEIC ACIDS ENCODING THE SAME
Examiner	:	Mary E. Mosher, Ph.D.

Group At Unit 1648

CERTIFICATE OF EXPRESS MAILING

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 C.F.R. §1.10 on the date indicated below and addressed to Box Non Fee Amendment, Commissioner for Patents, Washington, D.C. 20231.

EXPRESS MAIL NO: EV194297115US

February 19, 2003
(Date)

Tiffany Bell

RESPONSE TO OFFICE ACTION

BOX FEE AMENDMENT
Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Responsive to the Office Action mailed on September 23, 2002 in connection with the above-identified patent application, please consider the following arguments. The present Response is accompanied by a request for a two-month extension of time and the requisite fee, therefore, it is timely filed.

Priority

The Examiner has requested that applicants provide the serial number and specific page number(s) of any parent applications to which priority is desired, "which specifically supports the particular claim limitation for each and every claim limitation in

all the pending claims which applicant considers to have been in possession and fully enabled prior to July 1, 2001," the filing date of the present application.

Applicants submit that all claims pending in this application are fully supported by U.S. provisional application 60/062,816, filed on October 24, 1997. Specific support for the claims pending in the present application is to be found at least at the following locations in the 60/062,816 specification: paragraph bridging pages 1 and 2; page 2, first full paragraph; page 6, paragraph following the title "A. Full length PRO246 Polypeptide;"page 8, lines 18-24; page 18, line 25 through page 24, line 18, and Example 7. Since the original provisional application 60/062,816 was created using the "WordPerfect" software, but is available to the undersigned in a form converted to Microsoft Word only, the foregoing locations might differ slightly from the locations in the priority document.

Claim Rejections - 35 USC § 112

Claims 39-44 were rejected under 35 USC § 112, first paragraph as allegedly containing subject matter "which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." The Examiner dismissed the disclosure indicating that the PRO246 polypeptide is a novel cell surface virus receptor considering "the lack of information regarding viruses which associate with PRO246, and the absence of any evidence that any virus actually interacts with the putative receptor," and concluded that "undue experimentation would be required to use the claimed antibody."

Applicants respectfully disagree. The present application, and its earliest priority application 60/062,826 filed on October 24, 1997, disclosed that the PRO246 polypeptide shares significant homology to the human Coxsackie-adenovirus receptor. The disclosure further states that a portion of the PRO246 polypeptide has a significant

homology with the human cell surface protein HCAR. Considering its significant homology to the human Coxsackie adenovirus receptor, applicants further suggest the PRO246 polypeptide to be a novel cell surface virus receptor.

It was known in the art at the earliest priority date of the present application that HCAR is a human cellular receptor for the group B Cocksackie-viruses (CVB), and human subgroup C adenoviruses (Ad2 and Ad5) (see Tomko *et al., Proc. Natl. Acad. Sci. USA* 94:3352-3356 (April 1997), a copy of which is submitted with the attached Information Disclosure Statement). It was also well known that the Coxsackie-virus is involved in a variety of diseases, most prominently, human myocarditis, cardiomyopathy, meningoencephalitis, and acute pancreatis (see, e.g. column 2, lines 3-6 of US 5,942,606 of record). .Based on this general knowledge in the art, and the disclosure of the present application, one would appreciate that anti-PRO246 antibodies are expected to find utility in the prevention or treatment of viral disorders.

It is not necessary to provide a specific list of the viruses associated with the PRO246 to provide enabement. Virus assays were well known in the art at the earliest priority date of the present application, as demonstrated. for example, by the disclosure of Tomko *et al., supra*, and also by Example X of US 5,942,606. The results of such routine assays would be expected to provide the requested information concerning the specific viruses associated with the PRO246 polypeptide without undue experimentation. It is well established that the fact that some experimentation may be necessary, or time consuming, does not make such experimentation "undue," as long as the techniques used are readily available and routine, as they are in the present case.

The foregoing arguments are further supported by the issuance of US 5,942,606, disclosing a protein designated ACVRP, which is identical with the PRO246 polypeptide of the present application. The disclosure of US 5,942,606 is very similar to the disclosure of the present application, and is devoid of any experimental data

demonstrating the antiviral activity of ACVRP, or identifying the specific viruses associated with this receptor. The issuance of the presumptively valid US 5,942,606 is *prima facie* evidence that such experimental data are not required to comply with the requirements of patentability, including enablement. The same standard should be applied in the present case, which claims the priority of October 24, 1997, preceding the earliest priority date (November 24, 1997) of US 5,942,606. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the present rejection.

Claim Rejections - 35 USC § 102

Claims 39-44 were rejected under 35 USC 102(e2) or under 35 USC 102(b) as "being anticipated by Lal et al. 5,942,606." As discussed above, the present application is entitled to the priority date of October 24, 1997, which precedes, by one month, the earliest priority date of Lal et al. (November 24, 1997). Accordingly Lal et al. is not prior art against the present application, and the present rejection should be withdrawn.

Applicants note the additional art cited but not relied upon, none of which is believed to anticipate or render obvious the claims pending.

In conclusion, the present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited. Should the Examiner find that there are any further issues outstanding, she is invited to contact the undersigned attorney at the telephone number shown below.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 08-1641 (Docket No.: 39780-1618P2C22). A duplicate copy of this paper is enclosed.

Respectfully submitted,

Date: February 19, 2003

Ginger R. Dreger (Reg. No. 33,055)

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